

**REMARKS**

The pending Office Action addresses and rejects claims 1-7, 9, 10, 12-25, 27, and 28. Claims 7, 14-19, 21, and 22 have been previously withdrawn from consideration. Reconsideration is respectfully requested in view of the following remarks.

**Rejections Pursuant to 35 U.S.C. §102**

The Examiner rejects claims 1-6, 9, 10, 12, 13, 20, 23-25, 27, and 28 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Publication No. 2004/0078090 to Binette et al. (“Binette”). Applicants respectfully disagree.

Once again, Applicants submit herewith a copy of the 1.132 Declaration of Julia Hwang (the “Declaration”) in support of the patentability of Applicants’ invention. A rejection pursuant to 35 U.S.C. 102(e) can only properly be made if the invention was described in an application for patent *by another* before the invention by the applicant for patent. *See* 35 U.S.C. 102(e). The Declaration establishes that the invention disclosed in Binette and relied upon by the Examiner to reject the present claims was derived from the inventor of the present application. *See* Declaration at paragraphs 2 – 4. Therefore, the invention disclosed in Binette and relied upon by the Examiner to reject the present claims is not an invention *by another*.

Accordingly, in view of the Declaration, Applicants submit that the present rejection pursuant to 35 U.S.C. §102(e) is improper. Applicants request that the rejection be withdrawn.

**Rejections Pursuant to 35 U.S.C. §103**

The Examiner rejects claims 1-6, 9, 12-13, 20, 23-25 and 27-28 pursuant to 35 U.S.C. §103(a) as being unpatentable over Albrecht et al., “Closure of Osteochondral Lesions Using Chondral Fragments and Fibrin Adhesive,” Arch. Orthop. Trauma Surg. 101: 213-217 (1983), (“Albrecht”) in view of U.S Patent No. 6,485,723 to Badylak et al. (“Badylak”). Applicants respectfully disagree with the Examiner’s rejection.

Independent Claim 1

Claim 1 recites a biocompatible tissue implant for repairing a tissue injury or defect. The claimed three-part implant includes (a) an isolated biological tissue slice, (b) at least one minced tissue fragment, and (c) a retaining element. The at least one minced tissue fragment is combined with the isolated biological tissue slice. For example, minced tissue fragments can be added to an adhesive used to secure the implant or alternatively to a gel-like carrier applied to the implant. (See, e.g., paragraph 0040). The tissue slice is capable of acting as a cell source that allows viable cells to migrate out of the tissue slice. Similarly, the at least one minced tissue fragment also contains a plurality of viable cells that can migrate from the tissue fragment. Finally, a retaining element secures the tissue slice, and thereby the entire three-part implant, to the tissue site.

The Examiner admits that “Albrecht does not disclose an isolated biological tissue slice harvested from healthy tissue.” The Examiner thus relies on Badylak to remedy the deficiencies of Albrecht, arguing that “it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric scaffold of [Albrecht] with the SIS of [Badylak] in order to increase the biocompatibility of the implant.” However, even if such a modification would have been obvious to one of ordinary skill in the art – which it is not, for reasons discussed in more detail below – it would fail to teach the claimed invention because Badylak fails to teach or suggest an isolated biological tissue slice harvested from healthy tissue, much less a biological tissue slice capable of acting as a cell source that allows viable cells to migrate out of the tissue slice.

The Examiner continues to assert that Badylak “teaches a biocompatible tissue implant comprising a naturally occurring biocompatible tissue slice.” The Examiner also asserts that “the tissue slice [includes] an effective amount of viable cells” and that “cells can migrate out of the tissue.” The Examiner is incorrect. Badylak fails to teach or suggest a biological tissue slice harvested from healthy tissue that is capable of acting as a cell source. Badylak merely discloses a tissue graft construct that is formed from a submucosa matrix material. *See* Badylak at col. 2, lines 63-66 and col. 3, lines 59-61. First, the submucosal tissue that is processed into the submucosa matrix material is not harvested from healthy tissue, but is merely “a plentiful by-product of commercial meat production operations.” *See* Badylak at col. 2, lines 25-29. Second,

the submucosa matrix material disclosed by Badylak is not capable of acting as a cell source. The submucosa matrix material is produced by processing vertebrate intestinal material. *See* Badylak at col. 4, lines 1-14) Badylak discloses that the resulting submucosa matrix is substantially acellular after processing. *See* Badylak at col. 2, lines 30-33. Thus, although Badylak teaches that the matrix can be seeded with cells prior to implantation, the source of the cells is not the acellular submucosa matrix. Badylak therefore fails to remedy the deficiencies of Albrecht regarding an isolated biological tissue slice, harvested from healthy tissue, that is capable of acting as a cell source, as required by claim 1. Therefore, in light of the deficiencies in the teachings of both Badylak and Albrecht, the combination would fail to teach or suggest the claimed invention.

Moreover, the Examiner has not only disregarded the deficiencies in the references, but has failed to make out a prima facie case of obviousness. In order to make out an obviousness rejection, the Examiner must provide clear reasons why the person of ordinary skill would make the leap from the prior art to the claims. *See In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds ***cannot be sustained by mere conclusory statements***; instead, there ***must be some articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness") (emphasis added). Without providing reasoning with some rational underpinning, the Examiner easily falls prey to improper hindsight reasoning:

A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. *See Graham*, 383 U.S., at 36, 86 S. Ct. 684, 15 L. Ed. 2d 545 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to "'guard against slipping into the use of hindsight'".) *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007).

Here, the Examiner has provided references that, when combined, would not result in the claimed invention. The Examiner also fails to provide any articulated reasoning to support the proposed modification. The Examiner merely argues that it would have been obvious to "modify the polymeric scaffold of [Albrecht] with the SIS of [Badylak] in order to increase the biocompatibility of the implant." Such a conclusory statement lacks any of the required articulated reasoning or any rational underpinnings. Finally, the modification suggested by the Examiner is unsupported by the teachings of the references, and it fails the "predictability" test

articulated by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742 (Apr. 30, 2007) and articulated in the exemplary rationales that may support a conclusion of obviousness outlined in the MPEP. *See* MPEP at 2143.

Accordingly, independent claim 1 distinguishes over Albrecht in view of Badylak and represents allowable subject matter. Claims 2-6, 9, 12, 13 and 28 distinguish over the cited art at least because they depend from claim 1. The Examiner's rejection fails to address dependent claim 10. Applicants submit that claim 10 likewise distinguishes over the cited art at least because it depends from claim 1.

*Independent Claim 20*

Claim 20 recites a method for repairing tissue injury or defect. The claimed method comprises providing (i) an isolated biological tissue slice harvested from healthy tissue that is capable of acting as a source of viable cells; and (ii) at least one minced tissue fragment containing a plurality of viable cells that can migrate from the tissue fragment. The method further comprises applying the at least one minced tissue fragment to the isolated biological tissue slice to form a biocompatible tissue implant. For example, minced tissue fragments can be added to an adhesive used to secure the implant or alternatively to a gel-like carrier applied to the implant. (See, e.g., paragraph 0040).

As discussed above, the Examiner admits that "Albrecht does not disclose an isolated biological tissue slice harvested from healthy tissue." Moreover, Badylak fails to teach or suggest a biological tissue slice harvested from healthy tissue that is capable of acting as a source of viable cells or at least one minced tissue fragment containing viable cells. Thus, claim 20 distinguishes over Badylak for at least the reasons discussed above with respect to claim 1.

Accordingly, independent claim 20 distinguishes over Badylak and represents allowable subject matter. Claims 23-25 and 27 distinguish over the cited art at least because they depend from claim 20.

***Obviousness-Type Double Patenting Rejection***

The Examiner provisionally rejects claims 1-6, 9, 10, 12, 13, 20, 23-25, 27, and 28 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-27 of co-pending Application No. 10/374,772.

Applicants believe that all pending claims are allowable. Applicants will file appropriate terminal disclaimers if so warranted.

**Conclusion**

In conclusion, Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,

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